Attorney Docket No.: 2001-0116A Application No.: 09/,762,230

December 12, 2003

#### **REMARKS**

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks.

### I. CLAIM STATUS & AMENDMENTS

As correctly stated in the Office Action Summary, claims 16-30 were pending in this application when last examined. Claims 16, 21, and 23-30 are rejected. Claims 17-20 and 22 are objected to. The present amendment amends claims 16, 21 and 23. Upon entry of the present amendment, claims 16-30 will be pending in this application. Applicants reserve the right to file a continuation or division application on any canceled subject matter.

Support for the amendments to claims 16, 21 and 23 can be found in the Specification, for example, at page 11, lines 22-25 and page 12, line 2. Therefore, no new matter has been added by this amendment.

#### II. FORMAL MATTERS

#### A. Applicants' Priority Date

Acknowledgment has been made of the claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f), as well as the receipt of all certified copies of the foreign priority documents. See June 12, 2003 Office Action, Item 13 (a)(1).

### B. Drawings

The Examiner has acknowledged that the drawings filed on February 5, 2001 are accepted. See June 12, 2003 Office Action, Item 10.

### C. Information Disclosure Statements

Applicants request that the Examiner consider the Information Disclosure Statement ("IDS") along with the references cited therein that was submitted February 5, 2001. Enclosed herewith is a copy of the IDS along with a postcard receipt evidencing this submission.

Attorney Docket No.: 2001-0116A Application No.: 09/,762,230 December 12, 2003

## III. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 16, 21, and 23-30 stand rejected under 35 U.S.C. § 112, first paragraph, because the Specification, while enabling for an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or an isolated polynucleotide comprising SEQ ID NO: 1 purportedly does not reasonably provide enablement from any other embodiment. This rejection contains typographical errors in that the Examiner presumably intended to mean "amino acid sequence of SEQ ID NO: 10 or an isolated polynucleotide comprising SEQ ID NO: 2" as set forth in the claims. Applicants respectfully traverse this rejection for the following reasons.

The present amendment obviates this rejection in that it would not take an undue amount of experimentation for one of skill in the art to identify and isolate a nucleotide sequence having at least 95% homology with the nucleotide sequence of SEQ ID NO: 2 that also encodes a protein having piperidine-6-carboxylic acid dehydrogenase activity. Likewise, it would not take an undue amount of experimentation for one of skill in the art to isolate a nucleotide sequence which hybridizes under stringent conditions at 60°C in 2X SSC to a sequence of SEQ ID NO: 2 that still encodes a protein having the requisite activity. In this regard the Specification at page 11, line 20 to page 12, line 2 and page 23, line 18 to page 24, line 1 discloses common methods and techniques for finding such sequences. Moreover the Specification at page 23, line 18 to page 24, line 16 actually demonstrates the cloning of a nucleotide sequence encoding a protein having the requisite activity. For instance the Specification teaches and even demonstrates a DNA sequence of about 2.5 kpb that was integrated into a plasmid i.e., pCF235. This sequence had an ORF encoding 510 amino acids starting from the ATG of the 2855th of the base sequence of SEQ ID NO: 2 and ending at the TAA at the 4387th of the base sequence. This amino acid sequence was subjected to homology search BLAST, and showed high homology with a known amino acid sequence of a piperidine-6-decarboxylic acid dehydrogenase. Given such a teaching along with the high level of skill in the art, the skilled artisan would easily be able to isolate and identify other nucleotide sequences having high percent homology with the nucleotide sequence of SEQ ID NO: 2. The fact that experimentation may be complex does not initially make it undue, if the art typically engages in such experimentation. Also, the test of enablement is not whether any

Attorney Docket No.: 2001-0116A Application No.: 09/,762,230 December 12, 2003

experimentation is necessary, but whether it is undue. In this regard, Applicants submit that the amount of experimentation required to arrive at the claimed invention would be nothing more than the routine, and thus, not undue.

Furthermore, with regards to "stringent conditions", the claims have been amended to include the recitation of the specific stringent conditions set forth in the Specification.

Accordingly one skilled in the art would know and understand how to hybridize nucleotide sequences at such stringent conditions without undue experimentation.

Therefore, in view of the foregoing amendments and/or remarks, Applicants respectfully request the withdrawal of this rejection.

# IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 16, 23, and 24-30 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. See June 12, 2003 Office Action, page 30.

These claims have been amended to include a recitation of specific stringent conditions as outlined in the Specification, thereby obviating the Examiner's concern regarding the term "stringent condition".

Therefore, in view of the foregoing amendments and/or remark, Applicants respectfully request the withdrawal of this rejection.

#### V. OBJECTION TO THE CLAIMS

Claims 17-20 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable of rewritten in independent form including all the limitations of the base claims and any intervening claims. See June 12, 2003 Office Action, page 4. The present Amendment obviates the Examiner's rejection, thereby rendering the objection to the claims moot. Therefore, Applicants respectfully request the withdrawal of this objection.

Attorney Docket No.: 2001-0116A Application No.: 09/762,230 December 12, 2003

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the present application is in condition for allowance. Such allowance is solicited.

If Examiner Fronda believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to telephone on the undersigned at the number below.

Respectfully submitted,

Tadashi FUJII et al.

y:\_\_\_*UU* 

Warren M. Cheek, Jr.

Registration No. 33,367

Attorney for Applicants

WMC/JFW/nk Washington, D.C. 20006-1021 Telephone (202) 721-8200 Facsimile (202) 721-8250 December 12, 2003